

REMARKS/ARGUMENTS

The present application has been reviewed in light of the Office Action dated November 12, 2008. Claims 1-69 remain pending in this application. Claim 1 has been amended; and claims 12-69 have been previously withdrawn. Applicants respectfully request reconsideration of these rejections and reexamination of the above-identified application in view of the amendments made to the claims and the remarks below.

Applicants respectfully reserve the right to file at least one divisional application to non-elected claims 12-69.

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,395,033 to Byrne et al. (hereinafter "Byrne"). Applicants respectfully submit that claim 1, as amended herein, is allowable over Byrne.

MPEP §2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Applicants submit that Byrne does not anticipate each and every element of amended independent claim 1. Independent claim 1 presently recites at least one micro-electromechanical system (MEMS) device operatively connected to the surgical instrument for at least one of sensing a condition, measuring a parameter and controlling the condition and/or parameter adjacent the end effector; *wherein the at least one MEMS device is a single integral device that is operationally independent of other MEMS devices configured to communicate with the*

surgical instrument; and wherein at least one control operation of the surgical instrument is automatically adjusted based on feedback received from the at least one MEMS device via at least one comparator for comparing at least one of a second condition and a measured parameter against at least one predetermined value.

As seen in at least FIGS. 1-4 of the present disclosure (only FIG. 2 being reproduced below by way of example), the surgical stapling instrument includes several MEMS "M" that are single, standalone, and integral devices/units operating independently of each other to measure various desired parameters.

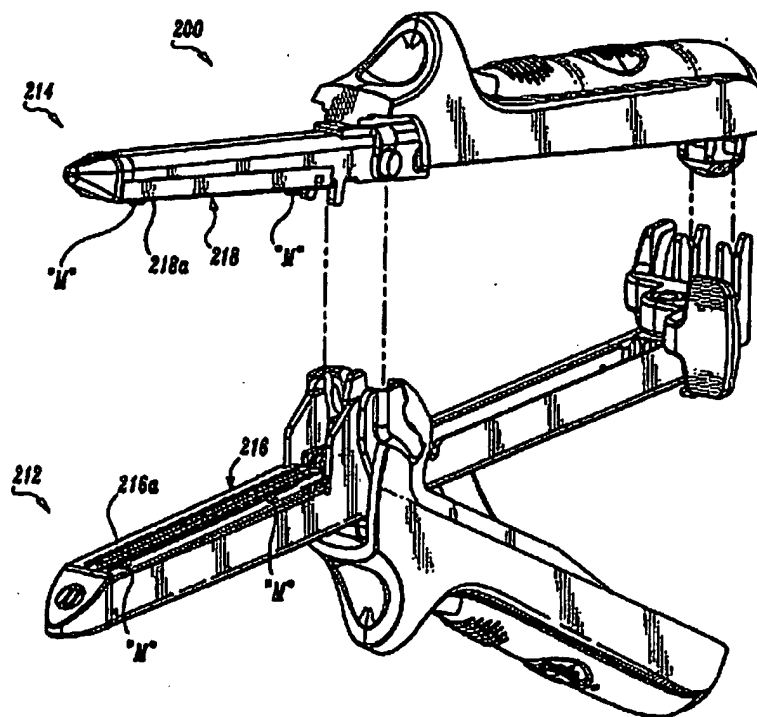
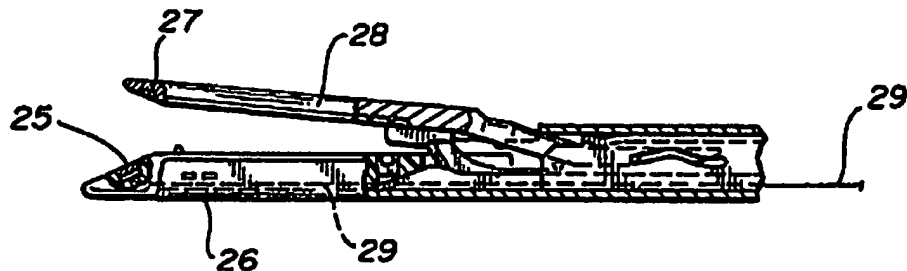


FIG. 2

Byrne does not disclose "...wherein the at least one MEMS device is a single integral device that is operationally independent of other MEMS devices configured to communicate with the surgical instrument," as recited in claim 1.

Byrne is directed to a surgical instrument that includes an electromagnetic sensor in the head of the instrument to determine tissue parameters. See column 1, lines 9-14. In particular, Byrne teaches and/or suggests, as seen in FIG. 2, a sensing mechanism 20 having an electromagnetic sensor 25 disposed in the distal end of the staple holding member 26 and a permanent magnet 27 disposed at the distal end of the anvil member 28. See column 3, lines 27-36.

FIG-2



Additionally, with regard to FIGS. 3a-3c, Byrne states that the sensor comprises a magneto-resistive sensor 34 and a biased magnet 35, where the magneto-resistive sensor 34 is disposed in a separate location relative to the permanent magnet target 32. See column 4, lines 6-13. In other words, Byrne utilizes at least two physically separate devices/units (e.g., a biased magnet 35 and a permanent magnet target 32) that must communicate with each other in order to obtain desired readings for various parameters.

FIG-3a

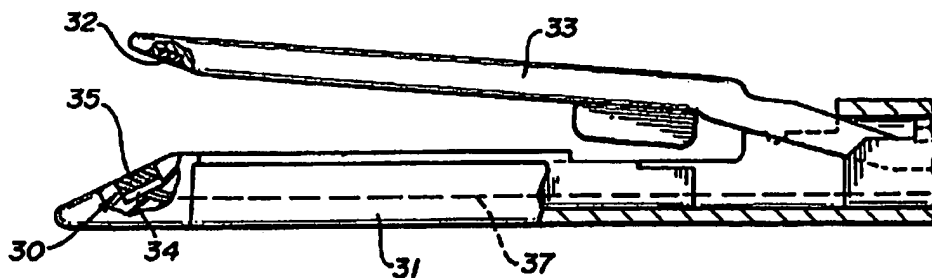


FIG-3b

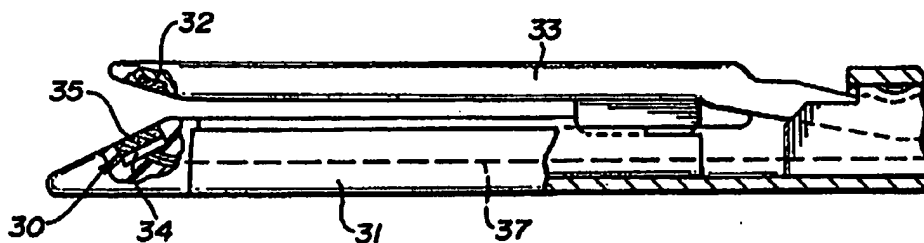
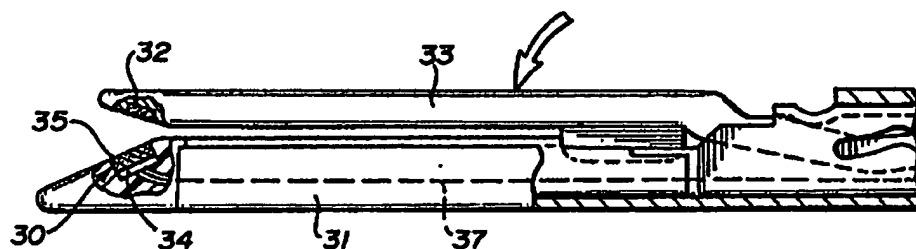


FIG-3c



According to Byrne, "[a]s can be appreciated, as the anvil member is brought in closer proximity to the staple holding member, the magneto-resistive sensor detects the strength of the magnetic field produced by the permanent magnet." (See column 3, lines 61-65). Byrne further states, "[i]n operation, the permanent magnet produces a magnetic field which is disposed outwardly towards the magneto-resistive sensor. As the anvil member is brought into closer proximity to the staple holding member, the magneto-resistive sensor will sense the strength and positioning of the magnetic field." (See column 4, lines 44-50).

In contrast, in the present disclosure, each sensing device is a single integral device that operates independently of other MEMS devices. For example, in the present disclosure, even one MEMS device, acting as a single, standalone, and integral unit would be capable of measuring various desired parameters and sending such collected information to a user.

The MEMS of the present disclosure require neither two physically separate opposing magnetic devices (FIGS. 1-6 of Byrne), nor two physically separate adjacent magnetic devices (FIG. 7 of Byrne) to measure desired parameters. In Byrne, two physically separate magnetic components (e.g., elements 32 and 35) are necessary in order to create a stabilizing magnetic field parallel to the sensors aligning field in order to prevent sensor flipping issues. See column 4 lines 13-21.

Additionally, the MEMS of the present disclosure are devices that each operate as one, single, standalone, integral device/unit, without the need to provide for an additional opposing device/unit (e.g., permanent magnet or element 32 of FIG. 3 of Byrne). Thus, the sensing mechanism 20 of Byrne requires secondary/supplemental/accessory components to operate properly because the sensing mechanism 20 is presented as partial or fractional components of a whole, whereas each MEMS of the present disclosure composes a complete, full, integral, and/or intact device/unit independently operational relative to other secondary/supplemental/accessory components.

Moreover, Byrne does not teach or suggest control operations that are automatically adjusted based on feedback received from the at least one MEMS device via at least one comparator for comparing at least one of a second condition and a measured parameter against at least one predetermined value. Byrne is not concerned with any type of feedback mechanism

for providing real-time information to a user of the surgical instrument in order to aid the user in making adjustments as the surgery is taking place.

Applicants therefore respectfully submit that, in view of the amendments made to claim 1 herein, and in view of the arguments presented above, that claim 1 is allowable over Byrne. Since claims 2-10 depend, either directly or indirectly, from claim 1 and contain all of the features of claim 1, for the arguments overcoming the rejection to claim 1 are applicable as well to claims 2-10.

Claim 11 was rejected under 35 U.S.C 103(a) as being unpatentable over Byrne, as applied to claim 9, in view of U.S. Application No. 2004/0267310 to Racenet et al. (hereinafter "Racenet"). Applicants submit that claim 11, is allowable over the applied combination of Byrne and Racenet.

Since claim 11 depends from claim 1 and contains all of the features thereof, for the reasons presented above regarding the patentability of claim 1, it is respectfully submitted that claim 11 is also patentable over Byrne in view of Racenet.

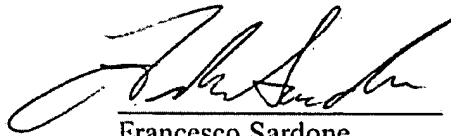
Additionally, the Examiner relies on Racenet for the disclosure of either a linear or annular surgical stapler. However, even assuming the teachings of Racenet proffered by the Examiner, Applicant submits that Racenet would fail to cure any deficiencies of Byrne as it relates to underlying independent claim 1 because Racenet fails to teach or suggest "...wherein the at least one MEMS device is a single integral device that is operationally independent of other MEMS devices configured to communicate with the surgical instrument," as recited in claim 1.

In view of the foregoing, for at least the reasons that amended independent claim 1 is allowable over Byrne in view of Racenet under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claim 11 is also allowable over Byrne in view of Racenet under 35 U.S.C. §103(a).

Accordingly, it is respectfully submitted that Applicants' amendments and/or remarks overcome the rejections of the present Office Action with respect to claims 1-11 and put said claims in condition for allowance. Applicants request reconsideration and reexamination of the application in view of the amendments made to the claims and the remarks above.

In light of these amendments and remarks, favorable consideration and allowance of all outstanding claims are earnestly solicited. Should there be any questions after the Examiner's review of this paper; the Examiner is invited to contact the undersigned at either of the numbers indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Francesco Sardone', written over a horizontal line.

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